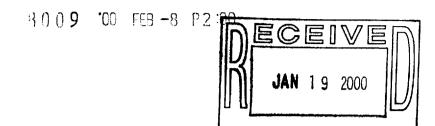


January 6, 2000



Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
 Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):

Over 50 clinical studies involving over 1,300 people conducted around the world demonstrate the multiple benefits of Vinpocetine supplementation. Key benefits include:

Memory Enhancement Cognitive Performance Cerebral Circulation Mental Acuity and Awareness

Vinpocetine enhances memory by improving cerebral circulation, promoting oxygen utilization and optimizing energy transport.

Vinpocetine increases energy use and improves the utilization of oxygen and glucose leading to healthy circulation in the brain. Glucose, the only energy source for the brain, is vital to optimal brain function. Clinical studies show that Vinpocetine increases mental acuity and awareness, thereby enhancing overall cognitive performance.

975 - 0162

LET 4881



Cognitive Performance. Forty two people received Vinpocetine in the following amounts: 10 mg three times a day for 30 days followed by 5 mg three times a day for an additional 60 days. The other 42 people received matching placebo tablets for the entire 90 day period. The results demonstrate that the people taking Vinpocetine scored consistently better on multiple evaluations and showed significant improvement over placebo.

Cerebral Vasodilation. Vinpocetine was clinically shown to promote blood vessel relaxation, increase fluidity of the blood, invigorate red blood cells, and remove blockage leading to improved cerebral vasodilation and circulation in the brain without increasing blood pressure or pulse rate.

Hypoxia. Clinical studies also demonstrate a protective effect when Vinpocetine was supplemented to reduce the consequences of low oxygen. Vinpocetine may provide significant benefits to anyone who performs at high altitudes such as skiers, hikers and mountain climbers by promoting the utilization of oxygen in the brain.

Both Vinpocetine and ginkgo flavone glycosides are effective in increasing peripheral circulation. However, Vinpocetine's ability to specifically improve cerebral circulation has been well documented in clinical studies. These studies demonstrate significant observable enhanced memory effects within a few days, whereas ginkgo supplementation has typically shown to require longer periods of intake before marked results were observed.

Over 50 clinical studies, some of which extend for as long as one year, and decades of use in Europe and Asia attest to Vinpocetine's safety and ability to improve overall brain function. In clinical studies, when compared with placebo, Vinpocetine has been shown to be well tolerated and has demonstrated an incidence of side effects similar to and sometimes lower than placebo.

- (3) Name of the dietary ingredient if not provided in the text of the statement: see above
- (4) Name of the dietary supplement: products containing Vinpocetine as a single ingredient or in combination with other ingredients



The above statement(s) may be used in one or more of the following brands of products: Nature Made, Sunny Maid, Nature's Resource, AAFES, AARP, Osco, Sav-On, Valu Wise, Bartell Drug, CVS, Duane Reade, Walgreens, Longs, Spring Valley, Brite Life, Family Pharmacy, GNP, Valu-Rite.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

David Kropp

Acting Director, Regulatory and Consumer Affairs